IN THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

STATE OF KANSAS, et al., Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., et al., Defendants-Appellees.

OPENING BRIEF OF APPELLANTS

Appeal from the
United States District Court for the Northern District of Iowa
Hon. Leonard T. Strand, District Judge
Case No. 1:24-cv-00110

KRIS W. KOBACH

Kansas Attorney General

Anthony J. Powell
Solicitor General
Adam T. Steinhilber
Assistant Solicitor General
James R. Rodriguez
Assistant Attorney General

Office of the Kansas Attorney
General
120 SW 10th Avenue, 2nd Floor
Topeka, Kansas 66612
Telephone: (785) 296-2215
Fax: (785) 296-3131
anthony.powell@ag.ks.gov
adam.steinhilber@ag.ks.gov
jay.rodriguez@ag.ks.gov
Counsel for Plaintiff State of Kansas
(additional counsel on signature page)

SUMMARY AND ORAL ARGUMENT STATEMENT

In May 2024, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) implemented a Rule governing facilities that participate in the Medicare and Medicaid programs. See 89 Fed. Reg. 40,876 (May 10, 2024). The Rule sets minimum staffing standards by mandating a registered nurse (RN) be onsite 24/7 and by providing the minimum staff hours per resident day (HPRD) the facilities must meet. It also requires facilities to make and update an enhanced facility assessment (EFA), and it imposes certain reporting requirements on States.

Plaintiffs—a diverse group of nursing homes, organizations whose members are nursing homes, and States—sued Defendants, asserting the Rule is unlawful. Plaintiffs then moved for a preliminary injunction, arguing the Rule irreparably harms them by forcing them to spend money in compliance. The district court refused to enjoin the Rule, principally because it found certain irreparable harm too speculative. It then denied Plaintiffs' request for an injunction pending appeal.

Plaintiffs believe oral argument will aid the Court in this complex regulatory dispute, and they request twenty minutes per side.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1A:

LeadingAge Kansas states that it is a Kansas nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge South Carolina states that it is a South Carolina nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Iowa states that it is an Illinois nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

Leading Age Colorado states that it is a Colorado nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Maryland states that it is a Maryland nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Michigan states that it is a Michigan nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Minnesota states that it is a Minnesota nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Missouri states that it is a Missouri nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Nebraska states that it is a Nebraska nonprofit corporation, that it is not a subsidiary of any corporation, and that it

does not have any stock which can be owned by a publicly held corporation.

LeadingAge New Jersey/Delaware states that it is a New Jersey nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Ohio states that it is an Ohio nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Oklahoma states that it is an Oklahoma nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge PA states that it is a Pennsylvania nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

South Dakota Association of Healthcare Organizations states that it is a South Dakota nonprofit corporation, that it is not a subsidiary of

any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Southeast states that it is a Florida nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Tennessee states that it is a Tennessee nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

LeadingAge Virginia states that it is a Virginia nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

Dooley Center states that it fully owned by Mount St. Scholastica, a nonprofit Catholic Monastery, with a governing body comprised of Sisters of Mount St. Scholastica. It does not have any stock which can be owned by a publicly held corporation.

Wesley Towers states that it is a Kansas nonprofit corporation, that it is not a subsidiary of any corporation, and that it does not have any stock which can be owned by a publicly held corporation.

TABLE OF CONTENTS

SUMMARY AND ORAL ARGUMENT STATEMENT	i
DISCLOSURE STATEMENT	ii
TABLE OF AUTHORITIES	X
INTRODUCTION	1
STATEMENT OF JURISDICTION	3
STATEMENT OF THE ISSUE	4
STATEMENT OF THE CASE	4
I. Statutory and regulatory background	4
II. The Rule	9
a. The Abt Study	9
b. Promulgation	11
c. Requirements	13
d. The staffing mandates' flaws	15
III. Plaintiffs	17
IV. Previous proceedings	22
SUMMARY OF THE ARGUMENT	23
ARGUMENT	24

I.	1	The Rule irreparably harms Plaintiffs through unrecoverab	ble
	n	nonetary harm	26
a.	EFA	A requirement	28
b.	Sta	ffing mandates	32
c.	The	Rule uniquely harms State Plaintiffs	36
II	. I	Plaintiffs are likely to succeed on the merits	37
a.	The	Rule is unauthorized agency action that upends a nation	wide
	ind	ustry	37
	i.	The Rule triggers the major questions doctrine	38
	ii.	Congress did not authorize the Rule	41
	iii.	Constitutional concerns	47
b.	The	Rule contradicts Congress' careful decision on staffing	48
c.	The	Rule is arbitrary and capricious	50
	i.	Sharp departure	52
	ii.	Reliance interests	53
	iii.	Important aspects of the problem	57
II	I. 1	The equities and public interest lie with Plaintiffs	63
17	7. N	Nationwide relief is necessary	65
) N	ICT T	ISION	66

CERTIFICATE OF COMPLIANCE	. 74
CERTIFICATE OF SERVICE	.75

TABLE OF AUTHORITIES

Cases

Alab. Ass'n of Realtors v. Dep't of Health and Hum. Servs., 594 U.S. 758 (2021)	38, 39, 41
Alexander v. Sandoval, 532 U.S. 275 (2001)	48
Barr v. Am. Ass'n of Pol. Consultants, Inc., 591 U.S. 610 (2020)	65
Brakebill v. Jaeger, 932 F.3d 671 (8th Cir. 2019)	25
Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc., 815 F.2d 500 (8th Cir. 1987)	25
Carpenters Indus. Council v. Zinke, 854 F.3d 1 (D.C. Cir. 2017)	35
D. Ginsberg & Sons, Inc. v. Popkin, 285 U.S. 204 (1932)	44
D.C. v. U.S. Dep't of Agric., 444 F. Supp. 3d 1 (D.D.C. 2020)	27, 66
Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109 (8th Cir. 1981)	25
Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 591 U.S. 1 (2020)	50
Dubin v. United States, 599 U.S. 110 (2023)	44

Encino Motorcars, LLC v. Navarro, 579 U.S. 211 (2016)	52, 56
Entergy, Ark., Inc. v. Nebraska, 210 F.3d 887 (8th Cir. 2000)	26
FCC v. Fox Television Stations, Inc., 556 U.S. 502 (2009)	51
FCC v. Prometheus Radio Project, 592 U.S. 414 (2021)	50
Gen. Motors Corp. v. Harry Brown's, LLC, 563 F.3d 312 (8th Cir. 2009)	26
Glenwood Bridge, Inc. v. City of Minneapolis, 940 F.2d 367 (8th Cir. 1991)	63
Gonzales v. Oregon, 546 U.S. 243 (2006)	42
Gundy v. United States, 588 U.S. 128 (2019)	47
In re Operation of Mo. River Sys. Litig., 421 F.3d 618 (8th Cir. 2005)	51
Iowa Utilities Bd. v. F.C.C., 109 F.3d 418 (8th Cir. 1996)	26
Kansas v. United States, 124 F.4th 529 (8th Cir. 2024)	64
Kentucky v. Biden, 23 F.4th 585 (6th Cir. 2022)	48
La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355 (1986)	41

Michigan v. EPA, 576 U.S. 743 (2015)		. 51
Missouri v. Biden, 112 F.4th 531 (8th Cir. 2024)	29, 30, 37,	39
Missouri v. Trump, Nos. 24-2332, 24-2351, F.4th, 2025 WL 518130 (8th Cir. Feb. 18, 2025) 4, 25, 26, 29, 3		
Mistretta v. United States, 488 U.S. 361 (1989)		. 47
Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safe Admin., 595 U.S. 109 (2022)		
Nat'l Min. Ass'n v. U.S. Army Corps of Engineers, 145 F.3d 1399 (D.C. Cir. 1998)		. 65
Nebraska v. Biden, 52 F.4th 1044 (8th Cir. 2022)	33, 64, 65,	66
New York v. Yellen, 15 F.4th 569 (2d Cir. 2021)		. 35
Packard Elevator v. I.C.C., 782 F.2d 112 (8th Cir. 1986)		. 32
RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639 (2012)	44,	46
Rodgers v. Bryant, 942 F.3d 451 (8th Cir. 2019)		. 65
S&M Constructors, Inc. v. Foley Co., 959 F. 2d 97 (8th Cir. 1992)		. 25

Shawnee Tribe v. Mnuchin, 984 F.3d 94 (D.C. Cir. 2021)	64
Texas v. United States, 40 F.4th 205 (5th Cir. 2022)	50, 62
Util. Air Regul. Group v. EPA, 573 U.S. 302 (2014)	38
Washington v. Reno, 35 F.3d 1093 (6th Cir. 1994)	64
West Virginia v. EPA, 597 U.S. 697 (2022)38	3, 39, 40
Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001)	41, 42
Statutes, Regulations, and Rules	
86 Stat. 1329, 1424–27 (Oct. 30, 1972)	6
101 Stat. 1330-161 (Dec. 22, 1987)	7
101 Stat. 1330-186	7
104 Stat. 1338 (Nov. 5, 1990)	7
Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965)	4
Pub. L. No. 92-603, § 278	6
Pub. L. No. 100-203, § 4201	7
Pub. L. No. 100-203, § 4211	7
Pub. L. No. 101-508, § 4008 (Nov. 5, 1990)	7

Pub. L. No. 101-508, § 4801(Nov. 5, 1990)	7
5 U.S.C. § 702	27
28 U.S.C. § 1292	4
28 U.S.C. § 1331	3
42 U.S.C. § 1302	1, 46
42 U.S.C. § 1395i-3	6, 49
42 U.S.C. § 1396r	6, 49
42 C.F.R. § 483.1	5
42 C.F.R. § 483.30	13
42 C.F.R. § 483.35	7
38 Fed. Reg. at 18,620 (July 12, 1973)	6
39 Fed. Reg. at 2,238, 2,239 (Jan. 17, 1974)	. 6, 7
45 Fed. Reg. at 47,368, 47,371, 47,387 (July 14, 1980)	7
80 Fed. Reg. at 42,168, 42,201 (July 16, 2015)	8
81 Fed. Reg. at 6,755	56
81 Fed. Reg. at 68,688, 68,754–56 (Oct. 4, 2016)	8
81 Fed. Reg. at 68,754	52
81 Fed. Reg. at 68,755	8, 52
81 Fed. Reg. at 68.756	52

81	Fed.	Reg.	at 68,758	52
88	Fed.	Reg.	at 61,35211,	16
88	Fed.	Reg.	at 61,366	59
88	Fed.	Reg.	at 61,36916,	59
89	Fed.	Reg.	40,876 (May 10, 2024)i, 11,	13
89	Fed.	Reg.	at 40,877	57
89	Fed.	Reg.	at 40,87912,	46
89	Fed.	Reg.	at 40,88035,	56
89	Fed.	Reg.	at 40,88111, 30, 40,	5 8
89	Fed.	Reg.	at 40,883	31
89	Fed.	Reg.	at 40,88614,	17
89	Fed.	Reg.	at 40,89012,	46
89	Fed.	Reg.	at 40,891	46
89	Fed.	Reg.	at 40,893	59
89	Fed.	Reg.	at 40,89460, 61,	62
89	Fed.	Reg.	at 40,902	61
89	Fed.	Reg.	at 40,905	15
89	Fed.	Reg.	at 40,90615,	31
89	Fed.	Reg.	at 40,90815,	5 3

89	Fed.	Reg.	at 40,909	31
89	Fed.	Reg.	at 40,911	34
89	Fed.	Reg.	at 40,912	34
89	Fed.	Reg.	at 40,9391	19
89	Fed.	Reg.	at 40,94917, 61, 6	32
89	Fed.	Reg.	at 40,95017, 6	32
89	Fed.	Reg.	at 40,95334, 49, 6	31
89	Fed.	Reg.	at 40,956	55
89	Fed.	Reg.	at 40,957	55
89	Fed.	Reg.	at 40,958	58
89	Fed.	Reg.	at 40,962, tbl. 18	20
89	Fed.	Reg.	at 40,9706	31
89	Fed.	Reg.	at 40,970, tbl. 22	17
89	Fed.	Reg.	at 40,977	58
89	Fed.	Reg.	at 40,978	58
89	Fed.	Reg.	at 40,979	58
89	Fed.	Reg.	at 40,980	58
89	Fed.	Reg.	at 40,984, tbl 282	20
89	Fed.	Reg.	at 40,99121, 3	36

89 Fed. Reg. at 40,995
89 Fed. Reg. at 40,99614, 45
89 Fed. Reg. at 40,997
89 Fed. Reg. at 40,99814
89 Fed. Reg. at 40,99915
89 Fed. Reg. at 41,000
19 C.S.R. § 20-85.042
19 C.S.R. § 30-86.042
19 C.S.R. § 30-86.043
902 Ky. Admin. Reg. 20:048, § 2
902 Ky. Admin. Reg. 20:048, § 3
N.D. Admin. Code § 33-07-03.2-14
W. Va. Code R. § 64-13-8.14.155
W. Va. Code R. § 64-13-8.14.455
W. Va. Code R. § 64-13-8.14.5
Fed. R. App. P. 26.1ii
8th Cir. R. 26.1Aii
Other Authorities
Abt Associates, Nursing Home Staffing Study: Comprehensive Report viii (June 2023), https://tinyurl.com/b2ehy528

INTRODUCTION

Through the Rule, CMS¹ instituted a strict staffing mandate under the guise of a noble goal: better care for residents of long-term care (LTC) facilities. But CMS ignored reality. The Rule requires more nurses in the face of a nursing shortage. The Rule cannot make nurses appear out of thin air. Nor are its arbitrary HPRD standards grounded in the needs of residents. In fact, Congress and agencies repeatedly rejected similar quantitative mandates, instead preferring to promote discretion and flexibility for facilities. Further, the Rule requires LTC facilities to spend—and continue spending—money on EFAs, and States must also comply with various reporting requirements.

The Rule burdens LTC facilities and States through an unfunded mandate that disrupts a nationwide industry and costs billions of dollars. In the process of attempting to comply, reputable LTC facilities will run up costs, with some ultimately being forced to close. This, in turn, will leave their residents in the cold.

The Rule is a triple threat: a costly and disruptive regulation without clear legislative authorization that conflicts with statutes and

¹ Unless otherwise noted, "CMS" refers to all Defendants.

is arbitrary and capricious. It also irreparably harms Plaintiffs. So, they sued to stop it. They then moved to preliminarily enjoin the Rule nationwide. The district court rejected their request, despite agreeing that the Rule's EFA requirement would cause irreparable harm. Instead of considering whether any provision of the Rule (like the staffing mandates) was unlawful, and thus warranted enjoining the whole Rule, the court stopped its analysis after determining the EFA requirement was lawful. And because it found that any harm from the staffing mandates was too speculative, it did not consider whether the mandates were lawful.

When regulated entities spend money to comply with a federal rule and must keep spending to remain in compliance, they suffer irreparable harm. They can never recover that money. Because the Rule irreparably harms Plaintiffs (through an integrated policy imposing staffing mandates, EFAs, and reporting and compliance work), injunctive relief is necessary.

The Rule is unlawful. CMS implemented a regulation that costs billions of dollars in compliance and upends an industry that touches the lives of millions of Americans. And it did so without clear congressional authorization, instead relying on vague "other" authority. But if this "authority" means CMS can promulgate the Rule, the separation of powers has been severely undermined. This is particularly true here, given that Congress already set minimum staffing standards that reject CMS's approach. And the Rule is arbitrary and capricious. CMS did not reasonably explain its sharp departure from past practice, nor did it reasonably consider reliance interests and important aspects of the problem.

The public interest favors a flexible approach that allows LTC facilities the ability to address staffing based on the needs of residents. That is not what the Rule provides. And the balance of equities tips in Plaintiffs' favor because an injunction alleviates their burden without hurting CMS. The Rule's harm and illegality extend nationwide, so a nationwide solution is warranted. Accordingly, this Court should reverse and preliminarily enjoin the Rule nationwide.

STATEMENT OF JURISDICTION

The district court has federal question jurisdiction under 28 U.S.C. § 1331. The court denied Plaintiffs injunctive relief on January 16, 2025. App. 436; R. Doc. 95. Plaintiffs filed their Notice of Appeal

later that day, App. 457; R. Doc. 98, and they filed their Amended Notice of Appeal on January 22, App. 459; R. Doc. 104. This Court has interlocutory appellate jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUE

- Whether the district court abused its discretion by not preliminarily enjoining the Rule because the court engaged in a piecemeal analysis of irreparable harm.
 - Missouri v. Trump, Nos. 24-2332, 24-2351, --- F.4th ----, 2025
 WL 518130 (8th Cir. Feb. 18, 2025)
 - Missouri v. Biden, 112 F.4th 531 (8th Cir. 2024)
 - 42 U.S.C. § 1395i-3
 - 42 U.S.C. § 1396r

STATEMENT OF THE CASE

I. Statutory and regulatory background

In 1965, Congress established the Medicare and Medicaid programs. *See* Pub. L. No. 89-97, 79 Stat. 286 (July 30, 1965). Nursing homes that participate in Medicare, 42 U.S.C. § 1395i-3, and Medicaid, 42 U.S.C. § 1396r—collectively known as LTC facilities—are governed

by largely parallel statutory requirements.² CMS issues consolidated regulations for facilities in either program.³ 42 C.F.R. § 483.1.

The statutes currently require facilities use an RN for "at least 8 consecutive hours a day, 7 days a week," and provide 24-hour licensed nursing services "sufficient to meet the nursing needs of their residents." § 1395i-3(b)(4)(C)(i); § 1396r(b)(4)(C)(i)(I)–(II). They do not institute staffing quotas. And the Medicare⁴ and Medicaid⁵ statutes

² Unless otherwise noted, cited federal statutes are within Title 42 of the United States Code.

³ Unless otherwise noted, arguments about Medicaid facilities and requirements apply to Medicare facilities and requirements, and vice versa.

⁴ HHS may waive the requirement to employ an RN for more than 40 hours per week if: (1) the facility is "located in a rural area and the supply of skilled nursing services is not sufficient to meet the needs" of residents; (2) "the facility has one full-time [RN] who is regularly on duty at [facility] for 40 hours [per] week"; (3) the facility has patients whose physicians have shown that they do not require an RN or physician for 48 hours, or it has arranged for an RN or physician to provide necessary services when the full-time RN is not on duty; (4) "[HHS] provides notice of the waiver to the State long-term care ombudsman"; and (5) the facility notifies residents and their families of the waiver. See § 1395i-3(b)(4)(C)(ii)(I)–(V).

⁵ A State may waive the staffing requirements if: (1) the facility demonstrates that, despite diligent efforts, it was unable to recruit appropriate personnel; (2) granting a waiver will not endanger the health or safety of the facility's residents; (3) during times when an RN

permit LTC facilities to obtain waivers of these requirements. The history behind the statutory and regulatory requirements demonstrates that Congress and agencies (including CMS in a past life) have eschewed the current approach.

After Congress amended the Social Security Act to declare that all LTC facilities participating in Medicare or Medicaid provide "24-hour nurse service[s] which is sufficient" to meet patient needs, including employing at least one RN full-time, Pub. L. No. 92-603, § 278, 86 Stat. 1329, 1424–27 (Oct. 30, 1972), it also introduced nurse-staffing waiver provisions for rural facilities under specific conditions, see id. § 267, 86 Stat. at 1450. HHS's predecessor, through its Social Security Administration (SSA), proposed regulations in 1973 that aligned with these statutory requirements. See 38 Fed. Reg. 18,620 (July 12, 1973).

During the notice-and-comment period for the proposed 1973 regulations, SSA received comments urging it to deviate from Congress's flexible, qualitative approach to instead require a rigid

is unavailable, an RN or physician is able to respond to calls from the facility; (4) the appropriate State agency notifies the State long-term care ombudsman of the waiver; and (5) the facility informs its residents and their families of the waiver. See § 1396r(b)(4)(C)(ii)(I)–(V).

nurse-to-patient ratio. See 39 Fed. Reg. 2,238, 2,239 (Jan. 17, 1974). But SSA refused: "[T]he variation from facility to facility in the composition of its nursing staff, physical layout, patient needs and the services necessary to meet those needs precludes setting [a specific ratio]." Id.

In 1980, HHS began directly administering the Medicare and Medicaid programs; the staffing standard remained. The agency declined to implement specific ratios when it proposed a "general revision" of relevant regulations. *See* 45 Fed. Reg. 47,368, 47,371, 47,387 (July 14, 1980).

In 1987, Congress redefined nursing home categories and imposed uniform staffing requirements on LTC facilities by requiring an RN on duty for at least 8 hours per day, 7 days a week. See Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4201(a), 101 Stat. 1330-161 (Dec. 22, 1987); accord id. § 4211(a), 101 Stat. 1330-186. Congress included waiver provisions and commissioned studies to analyze staffing requirements—in particular "the appropriateness of establishing minimum caregiver to resident ratios." See Pub. L. No. 101-508, §§ 4008(h), 4801(a), 104 Stat. 1338 (Nov. 5, 1990). Congress did not implement mandatory ratios, and Defendants continuously

administered Congress's staffing standards without incident. See 42 C.F.R. § 483.35(a)–(b) (2016).

In 2016, CMS once again dismissed the push for mandatory staffing ratios and a 24/7 RN requirement. See 81 Fed. Reg. 68,688, 68,754–56 (Oct. 4, 2016). It concluded that a "one-size-fits-all approach" to staffing was not only "inappropriate[,]" but that "mandatory ratios" and a "24/7 RN presence" were concerning. Id. at 68,754–56, 68,758; see also 80 Fed. Reg. 42,168, 42,201 (July 16, 2015) (emphasizing importance of considering resident acuity levels). CMS determined regulations should "focus" "on the skill sets and specific competencies of assigned staff to provide the nursing care that a resident needs rather than a static number of staff or hours of nursing care." 80 Fed. Reg. at 42,201. Indeed, it cautioned that "establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population." Id. CMS also found a 24/7 RN requirement "could negatively impact the development of innovative care options, particular[ly] in smaller, more home-like settings," and that "geographic disparity in supply could make such a mandate

particularly challenging in some rural and underserved areas." 81 Fed. Reg. at 68,755.

II. The Rule

In February 2022, the Biden Administration departed from decades of practice to impose "reform" that would "establish a minimum nursing home staffing requirement." The White House, FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes (Feb. 28, 2022), https://pfs2.acl.gov/strapib/assets/EJCC_CMS_Fact_Sheet_e1218a2030_cc09811bef.pdf. Accordingly, it directed CMS to determine the necessary level and type of staffing. Id.

a. The Abt Study

To fulfill its directive, CMS contracted with Abt Associates to perform a staffing study. Abt Associates, *Nursing Home Staffing Study: Comprehensive Report* viii (June 2023), https://tinyurl.com/b2ehy528. Because the goal was to quickly issue the proposed regulation, the Abt Study was "conducted on a compressed timeframe" with data collected between June and December 2022. *Id.* at xix. The Study was completed and published in June 2023.

Consistent with the government's decades of prior practice, the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." *Id.* at 115. Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id.* at xi; *see also, e.g., id.* at xii, xiv, 19, 31–32, 115. The mandate would require between 43 and 90 percent of nursing homes to add more staff; could cost up to \$6.8 billion in compliance each year; and would increase annual total salaries per nursing home from as low as \$316,000 to \$693,000. *Id.* at 113–14.

The Abt Study did not provide CMS's desired support. For example, it did not conclude a minimum staffing requirement would result in definitive benefits. It provided data only for "potential" benefits. *Id.* at 121. And it did not conclude that a minimum staffing requirement would provide better healthcare outcomes for residents. The literature it reviewed "underscored" that there was no "clear eviden[tiary] basis for setting a minimum staffing level." *Id.* at xi.

The Study's inability to meaningfully support the desired regulation makes sense: The government had previously and repeatedly rejected similar proposals.⁶

b. Promulgation

CMS issued its proposed rule in September 2023. See 88 Fed. Reg. 61352 (Sept. 6, 2023). Despite over 46,000 public comments—some of which warned CMS that the proposed rule exceeded its statutory authority, contravened Congress's decision on staffing standards, and failed to consider barriers to compliance—CMS published the Rule in May 2024. See 89 Fed. Reg. at 40,876.

CMS claimed the minimum staffing standard is supported by "literature evidence, analysis of staffing data and health outcomes, [and] discussions with residents, staff, and industry." See id. at 40,877. Citing the Abt Study, CMS asserted there was enough evidence to conclude a staffing requirement was necessary. See id. at 40,881, 40,877. Yet it then acknowledged: "There is no clear, consistent, and universal methodology for setting specific minimum staffing standards,"

⁶ This is particularly remarkable given the Study's troubling disregard for staffing shortages and the potential unintended consequences of a national minimum staffing requirement. *See* Abt Study at xxi.

as evidenced by the 38 States and D.C. that have adopted their own nurse-to-patient ratios. *Id.* at 40,881. Disregarding that nationwide variability, the Abt Study's inconclusiveness, and the agency's prior practice, CMS pushed ahead.

In doing so, CMS asserted that "various" statutory provisions contain "separate authority" for its mandate, *see id.* at 40,879, 40,890–1:

- the Secretary of Health and Human Services may impose "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," § 1395i-3(d)(4)(B); § 1396r(d)(4)(B),
- a facility "must provide services and activities to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident in accordance with a written plan of care," § 1395i-3(b)(2); § 1396r(b)(2), and
- a facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident," § 1395i-3(b)(1)(A);
 § 1396r(b)(1)(A).

c. Requirements

The Rule imposes burdensome staffing, assessment, and reporting requirements on Plaintiffs. Importantly, the Rule institutes two mandatory staffing requirements for LTC facilities.

First, it triples the required hours per day of RN services as determined by Congress. See § 1395i-3(b)(4)(C)(i); § 1396r(b)(4)(C)(i). Specifically, it imposes a "24/7 requirement": LTC facilities must have an RN "onsite 24 hours per day, for 7 days a week that is available to provide direct resident care." 89 Fed. Reg. at 40,997.

Second, the Rule abandons Congress's flexible, qualitative requirement that facilities "provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents." § 1395i-3(b)(4)(C)(i); § 1396r(b)(4)(C)(i). Instead, the Rule requires that "[t]he facility must meet or exceed a minimum of 3.48 [HPRD] for total nurse staffing," which must include a "minimum of 0.55 [HPRD] for [RNs]," and a "minimum of 2.45 [HPRD] for nurse aides [(NAs)]." 89 Fed. Reg. at 40,996. Previously, federal regulations mirrored Congress's qualitative requirements to keep nursing staff available 24 hours per

⁷ Burdens specific to Plaintiff States are discussed later in this Brief.

day without specifying a quantitative staffing requirement. See 42 C.F.R. § 483.30; cf. 89 Fed. Reg. 40,876, 40,996–97.

Addressing waivers, the Rule permits Medicare participants to qualify for a statutory waiver of the 24/7 RN requirement, but not the HPRD requirements. 89 Fed. Reg. at 40,997–98. The Rule also permits Medicaid participants to qualify for the statutory waiver concerning the new 24/7 RN requirement and 0.55 RN HPRD requirement, but not for the 3.48 total nurse HPRD and 2.45 NA HPRD requirements. *Id.* at 40,997. The Rule proposes a "hardship exemption," ostensibly allowing partial relief from the 24/7 requirement and minimum HPRD requirements. *Id.* at 40,998.

The Rule allows LTC facilities to obtain a waiver only if they: (1) prove a significant local shortage of health care staff; (2) demonstrate unsuccessful recruitment efforts despite offering competitive wages; (3) document financial expenditures on staffing relative to revenue; and (4) publicly disclose their exemption status. *Id.* at 40,998. And even if granted, *see id.* at 40,886, the exemption only gives an 8-hour reprieve from the 24/7 RN requirement, leaving facilities with the requirement for at least 16 hours per day, 7 days per week, *id.* at 40,998.

Beyond staffing, the Rule requires LTC facilities to conduct a comprehensive evaluation of their facility, residents, staff, and resident families to determine staffing and other needs. In doing so, LTC facilities must ensure the "active involvement" of direct care staff and their representatives and "solicit and consider input" from residents, their representatives, and family members. *Id.* at 40,908, 40,905–06. Compliance is a continual burden, as LTC facilities must "review and update" the EFA at least annually, although CMS did not provide clear guidance on when updates are "necessary." *Id.* at 40,999. LTC facilities must also engage in "contingency planning," despite already having emergency plans in place. *Id.* at 41,000.

d. The staffing mandates' flaws

In mandating 24/7 RN presence and nationwide staffing ratios, CMS posed an unreasonable directive to LTC facilities that puts arbitrary numbers above patient needs.

CMS failed to adequately explain why it departed from statute to impose the 24/7 RN requirement. Nowhere did the Abt Study suggest that LTC facilities should require an on-site RN 24/7. CMS also did not explain how it determined its 3.48, 0.55, or 2.45 HPRD requirements.

Instead, it claimed that the 3.48, 0.55, and 2.45 HPRD levels "were developed using case-mix adjusted data sources." 89 Fed. Reg. at 40,877. It also asserted the 0.55 and 2.45 levels, but not the 3.48 level, were discussed during the notice of proposed rulemaking. *See id.* at 40,891; *see also* 88 Fed. Reg. at 61,352.

In the notice of proposed rulemaking, CMS suggested that based on findings from the Abt Study, additional data sources, "two listening sessions," and literature reviews, it proposed minimum staffing levels of 0.55 HPRD for RNs and 2.45 HPRD for NAs. 88 Fed. Reg. at 61369. But the Abt Study did not substantiate those specific levels. CMS also failed to establish how other data assessments support the staffing levels. CMS provided no rationale for the 3.48 HPRD requirement in either the notice of proposed rulemaking or the Rule, aside from vaguely stating it was developed using "case-mix adjusted data sources." 89 Fed. Reg. at 40,877.

CMS's minimum staffing ratios require LTC facilities to ignore the variability in resident acuity and needs. Some facilities with higher acuity residents may need greater staffing, while others with lower acuity residents may not require an RN present 24/7. CMS failed to

explain why the same staffing is necessary at all facilities. And CMS failed to meaningfully consider the ongoing shortage of nursing staff across the country; it only offered \$75 million to help "increase the [LTC] workforce," which it "expects" will be used for "tuition reimbursement." *Id.* at 40,885–86. But \$75 million—assuming the entire amount actually does help increase nursing staff for LTC facilities—is a minuscule fraction of the total compliance cost.

III. Plaintiffs

Plaintiffs are twenty states, two LTC facilities, and seventeen non-profit organizations that represent LTC facility members in twenty-one states. Each is incurring—and will continue to incur—economic and other harms from the Rule. The Rule itself projects compliance costs will exceed \$5 billion per year after full implementation. *Id.* at 40,970, tbl. 22; *see also id.* at 40,949. Outside studies have placed the cost at more than \$7 billion. *Id.* at 40,950.

The Rule already imposes large financial and administrative burdens that will only increase as full implementation nears. For example, Wesley Commons, an LTC facility and member of Plaintiff LeadingAge South Carolina, hired two additional RNs to ensure it can

comply with the EFA and 24/7 RN requirements, incurring extra costs of \$14,650 (without considering night and weekend shifts). See App. 249–50; R. Doc. 30-20 at 5–6. It also reinstated two full-time NAs because of the HPRD requirement, incurring additional yearly costs of \$66,560. See App. 249–50; R. Doc. 30-20 at 5–6. And its increased pay to retain and recruit staff is an additional \$164,428 per year. See App. 249–50; R. Doc. 30-20 at 5–6. Many other LTC facilities are similarly engaged in advanced hiring, changing staffing, providing enhanced benefits, and increasing recruitment efforts now to ensure compliance. See, e.g., App. 142–44; R. Doc. 30-10 at 7–9; App. 251; R. Doc. 30-20 at 7; App. 266–67; R. Doc. 30-22 at 8–9.

LTC facilities that have not already hired staff to comply with the Rule will do so soon. Those costs are significant burdens. And they are especially harmful in rural areas (where the required workforce simply does not exist) and in other tight labor markets. *See, e.g.*, App. 151; R. Doc. 30-11 at 7 (Kansas needs an additional 312 RNs and 601 NAs to meet the minimum staffing ratios, on top of the existing 2,360 RN and 663 NA job openings); App. 223–31; R. Doc. 30-18 at 7–15 (describing workforce shortages and additional yearly cost for Pennsylvania LTC

facilities of over \$689,000 per provider). Many facilities will be unable to absorb the costs as they continually rely on historically underfunded Medicaid and Medicare reimbursement while serving seniors who cannot afford the escalating cost of care.

LTC facilities that are motivated to provide sufficient care for their residents will incur substantial costs, and they may be required to rely on expensive temporary staffing agencies to fill gaps. Temporary staff may provide lower quality care because they are less familiar with and less invested in the residents' wellbeing. *See, e.g.*, App. 204; R. Doc. 30-16 at 4; App. 222; R. Doc. 30-18 at 6. But the Rule offers little choice, because it staffs to numbers, not needs. Increased costs will likely lead to reduced services and increased closures, shrinking long-term care availability and forcing many residents to facilities far from family and friends. *See, e.g.*, App. 151–54; R. Doc. 30-11 at 7–10; App. 295–97; R. Doc. 30-26 at 4–6; App. 223–31; R. Doc. 30-18 at 7–15; App. 124–26; R. Doc. 30-8 at 4–6.

The Rule also harms Plaintiffs through its EFA requirement, *e.g.*, App. 148–51; R. Doc. 30-11 at 4–7, which imposes significant administrative burdens. CMS estimated it would cost each facility

around \$4,955, which is optimistic. 89 Fed. Reg. at 40,939. For example, a LeadingAge Minnesota member has spent over \$10,000 on administrative costs on an EFA without knowing whether it is compliant. App. 170–71; R. Doc. 30-14 at 3–4. Plaintiff Dooley Center took about 16 hours to complete its EFA, approximately \$579.36 per month to stay in compliance. App. 287–89; R. Doc. 30-25 at 3–5. And Plaintiff Wesley Towers's EFA took 89 hours.8 App. 281–82; R. Doc. 30-24 at 3–4.

State Plaintiffs that operate facilities subject to the Rule will incur all these same costs and burdens. *See*, *e.g.*, App. 306; R. Doc. 30-28 at 3; App. 91, 94; R. Doc. 30-2 at 2, 5. For example, Idaho estimates the Rule's staffing requirements alone will cost it at least \$800,000 annually for each LTC facility. *See* App. 92; R. Doc. 30-2 at 3.

State Plaintiffs' harms extend beyond their LTC facilities. For example, in Indiana, where compliance will cost well over \$100 million, 89 Fed. Reg. at 40,962, tbl. 18; see also id. at 40984, tbl. 28, much of the

⁸ Underscoring the arbitrariness of the staffing mandates, the EFAs from Dooley Center and Wesley Towers demonstrate there is no need for 24/7 RN coverage at either facility. *See* App. 287–89; R. Doc. 30-25 at 3–5; App. 280–81; R. Doc. 30-24 at 2–3.

cost will be passed on to State health plans. And each State will face increased costs through the Medicaid and Medicare programs.

Minimum staffing requirements increase the cost of care that the federal government's reimbursement will not fully cover. *See* App. 111;

R. Doc. 30-5 at 5; *see also* App. 104–05; R. Doc. 30-4 at 5–6.

The Rule also harms States because they will substantially increase their administrative costs to comply with the Rule's institutional payment transparency reporting requirements. See 89 Fed. Reg. at 40,995; see also App. 102; R. Doc. 30-4 at 3; App. 98; R. Doc. 30-3 at 3; App. 118; R. Doc. 30-7 at 3. And States must maintain the reported information on a public website. The Rule acknowledges this requirement will cost the States at least \$183,851 in the first year. 89 Fed. Reg. at 40,991; see also, e.g., App. 93; R. Doc. 30-2 at 4. Further, the States must process waiver requests and investigate complaints about alleged noncompliance with the Rule, see App. 91–93; R. Doc. 30-2 at 2–4; App. 118–19; R. Doc. 30-7 at 3–4; App. 102–04; R. Doc. 30-4 at 3–5, both of which are likely to occur given the shortage of trained nurses, see App. 91–92; R. Doc. 30-2 at 2–3; App. 108–09; R. Doc. 30-5 at 2-3.

IV. Previous proceedings

On October 8, 2024, Plaintiffs sued CMS over the Rule. App. 24; R. Doc. 1.9 Two weeks later, Plaintiffs moved to preliminarily enjoin the Rule nationwide. See generally R. Doc. 30; R. Doc. 78.

The district court denied the motion. App. 436; R. Doc. 95. Even though it recognized compliance costs are irreparable harm, the court found the uncontroverted harms from the staffing mandate too speculative. App. 447–50; R. Doc. 95 at 12–15. And although it determined the EFA requirement irreparably harmed Plaintiffs, it limited its analysis to whether the EFA requirement was unlawful; it did not address the lawfulness of the staffing mandates even though the EFA requirement provided inseverable support for the staffing mandates. App. 451–52; R. Doc. 95 at 16–17.

Plaintiffs unsuccessfully moved for a stay pending appeal in the district court. See R. Doc. 102; App. 458; R. Doc. 103. Plaintiffs then moved for a stay in this Court, where the request remains pending.

⁹ Three days later, Plaintiffs filed an amended complaint. See R. Doc. 3-1; see also App. 308; R. Doc. 37.

SUMMARY OF ARGUMENT

Throughout this proceeding, Plaintiffs have maintained that the entire Rule is unlawful in myriad ways and—as established through uncontroverted evidence—irreparably harms them. Because the public has no interest in an unlawful regulation (and certainly not one as disruptive as this) whose harm and illegality are not confined to Plaintiffs, this Court should preliminarily enjoin the Rule nationwide.

First, the Rule irreparably harms Plaintiffs because it required—and will continue to require—them to spend money to comply. In the midst of a nationwide nursing shortage, Plaintiffs must hire and retain nurses to satisfy the staffing mandates. And this shortage means Plaintiffs must begin working toward compliance now. Further, Plaintiffs have already spent time and money creating EFAs and must continually spend money updating them. State Plaintiffs will suffer unique harms from increased reporting and oversight.

Second, the Rule is (at least) triply unlawful. The Rule upends the nursing home industry and costs billions of dollars, triggering the major questions doctrine. But Congress has not specifically authorized this wide-reaching regulation. Accepting CMS's reliance on "general"

authority undermines the separation of powers. Indeed, the Rule conflicts with Congress's careful decision on staffing. And it is arbitrary and capricious: CMS sharply departed from past practice without reasonable explanation, failed to reasonably consider reliance interests, and failed to reasonably consider important aspects of the problem.

Finally, the equities and public interest lie with Plaintiffs. The Rule will severely harm Plaintiffs, CMS will suffer no harm from being unable to enforce an unlawful regulation, and the public has no interest in the government violating the law. And because the Rule is unlawful and harmful for each and every LTC facility and State, nationwide relief is appropriate.

ARGUMENT

The Rule is an impermissible agency power grab that upends a nationwide industry. Because the Rule comes with staggering compliance costs already felt by Plaintiffs, the Rule is unlawful for numerous independent reasons, and the equities and public interest counsel against this unlawful agency action, this Court should preliminarily enjoin the Rule nationwide.

This Court reviews the denial a preliminary injunction for an abuse of discretion. Brakebill v. Jaeger, 932 F.3d 671, 676 (8th Cir. 2019). In considering whether to issue a preliminary injunction, this Court examines: (1) whether Plaintiffs are likely to succeed on the merits; (2) whether Plaintiffs will be irreparably harmed absent immediate relief; (3) whether the balance of equities from an injunction weighs in Plaintiffs' favor; and (4) whether the public interest favors immediate injunctive relief. See Dataphase Sys., Inc. v. C L Sys., Inc., 640 F.2d 109, 113 (8th Cir. 1981) (en banc); Missouri v. Trump, Nos. 24-2332, 24-2351, --- F.4th ----, 2025 WL 518130, at *6 (8th Cir. Feb. 18, 2025). While likelihood of success on the merits is generally the "most significant" factor, S&M Constructors, Inc. v. Foley Co., 959 F.2d 97, 98 (8th Cir. 1992), "[n]o single factor in itself is dispositive," Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc., 815 F.2d 500, 503 (8th Cir. 1987).

Plaintiffs meet—if not exceed—each factor, so this Court should issue a preliminary injunction.

I. The Rule irreparably harms Plaintiffs through unrecoverable monetary harm

The district court principally denied relief because it concluded Plaintiffs had not demonstrated enough irreparable harm. In other words, although it correctly believed the Rule's staffing mandates would adversely affect Plaintiffs, it then incorrectly employed a novel irreparable harm threshold for much of Plaintiffs' injuries. See, e.g., App. 447; R. Doc. 95 at 12. And it refused to consider irreparable harm from the EFA requirement as an inevitable result of the unlawful staffing mandates. See App. 451; R. Doc. 95 at 16.

Monetary loss is harm, and it becomes irreparable when damages are unavailable to replace it. See Iowa Utilities Bd. v. F.C.C., 109 F.3d 418, 426 (8th Cir. 1996); see also Gen. Motors Corp. v. Harry Brown's, LLC, 563 F.3d 312, 319 (8th Cir. 2009). When a plaintiff cannot recover damages due to a defendant's immunity, monetary harm is irreparable and so relief lies only in equity. See Missouri, 2025 WL 518130, at *10; see also Entergy, Ark., Inc. v. Nebraska, 210 F.3d 887, 899 (8th Cir. 2000) (recognizing that when "[r]elief in the form of money damages" may be barred by sovereign immunity, "[t]he importance of preliminary

injunctive relief is heightened"). The Administrative Procedure Act (APA) only waives the federal government's sovereign immunity against injunctive relief; it does not permit monetary damages for an unlawful regulation. See D.C. v. U.S. Dep't of Agric., 444 F. Supp. 3d 1, 34 (D.D.C. 2020); 5 U.S.C. § 702 (allowing relief "other than money damages"). Because Plaintiffs can never recover damages for complying with Rule, their spending is irreparable harm warranting injunctive relief.

The Rule has cost—and will continue to cost—Plaintiffs money.

Even the district court conceded the Rule itself "acknowledge[d] that costs will be incurred before the respective implementation dates." App. 441; R. Doc. 95 at 6. And the court found the EFA requirement currently causes Plaintiffs to spend money. App. 451; R. Doc. 95 at 16.

Indeed, the Rule will likely cost each LTC facility hundreds of thousands of dollars annually. For example, in South Carolina, the estimated implementation cost is over \$550,000 per nursing home. *See* App. 247–48; R. Doc. 30-20 at 3–4. The cost is even greater in Pennsylvania, with over \$689,000 in additional annual costs per provider. App. 223–24; R. Doc. 30-18 at 7–8. Most LTC facilities cannot afford this significant financial strain and will be forced to serve fewer

patients, especially Medicare and Medicaid patients, or close their doors entirely. *See, e.g.*, App. 142–43; R. Doc. 30-10 at 7–8; App. 290; R. Doc. 30-25 at 6; App. 283; R. Doc. 30-24 at 5; App. 228; R. Doc. 30-18 at 12.

The district court considered irreparable harm as a threshold matter. App. 443; R. Doc. 95 at 8. And it correctly determined the Rule's EFA requirement irreparably harms Plaintiffs. App. 451; R. Doc. 95 at 16. The court nevertheless erroneously applied a selective and piecemeal analysis of the harm. But when properly analyzing Plaintiffs' arguments in light of their uncontroverted evidence, the harm is apparent. Because Plaintiffs' spending to comply with the Rule is "irreversible," see Nebraska v. Biden, 52 F.4th 1044, 1047 (8th Cir. 2022) (per curiam), the harm is irreparable.

a. EFA requirement

Effective since August 8, 2024, the Rule's EFA requirement irreparably harms Plaintiffs. As previously noted, this requirement results in LTC facilities spending money to develop and *continually update* their EFAs. As the district court properly recognized, this is irreparable harm. App. 451; R. Doc. 95 at 16.

But instead of analyzing Plaintiffs' likelihood of success on the merits for the Rule as a whole, the district court considered likelihood of success only with respect to the EFA requirement. The court also did not determine the EFA requirement was severable, declining to perform any severability analysis. App. 456 n.11; R. Doc. 95 at 21 n.11. Absent a determination that CMS intended the Rule to operate without the unlawful provision and that the Rule can so operate, the Rule must be considered as a whole when considering injunctive relief. *See Missouri*, 2025 WL 518130, at *11. The district court erred by not requiring CMS to show the Rule was severable; the Rule should have been enjoined because an inseverable part (this requirement) irreparably harms

The district court did not cite any case to support splitting up the Rule, which goes against this Court's precedent. In *Missouri v. Biden*, 112 F.4th 531 (8th Cir. 2024) (per curiam), this Court enjoined the

¹⁰ To be clear, the Rule's other requirements also cause irreparable harm sufficient for injunctive relief. But Plaintiffs lead with the EFA requirement because the district court agreed it irreparably harms them. And it is the easiest basis on which to issue a preliminary injunction: The requirement is effective, has caused Plaintiffs to spend unrecoverable money, and will continue to cause Plaintiffs to spend unrecoverable money.

entire student debt repayment and forgiveness rule pending appeal,
despite the district court finding that only one provision—the ultimate
forgiveness provision—imposed irreparable harm.

The district court here asserted the *Missouri* injunction was issued "only because the Government created a hybrid rule that made the district court's injunction useless." App. 452; R. Doc. 95 at 17. But that is incorrect. If the hybrid rule caused irreparable harm by enabling continuing loan forgiveness despite the district court injunction, this Court could have enjoined the loan forgiveness provision of the hybrid rule. Instead, it enjoined the entire rule because the entire rule facilitated irreparable harm. This Court recently affirmed that the entire rule and the hybrid rule should be preliminarily enjoined nationwide. *See Missouri*, 2025 WL 518130, at *12.

Here, the EFA requirement is a not a severable, unconnected provision. It is inseparable support for the staffing mandates. The Rule repeatedly acknowledges the EFA requirement's vital role in moving LTC facilities toward compliance with the mandates. 11

 $^{^{11}}$ See, e.g., 89 Fed. Reg. at 40,881 ("[N]ational minimum staffing standards in LTC facilities and the adoption of a 24/7 RN and [EFA] requirements, will help to advance equitable, safe, and quality care

The EFA requirement is essential to the Rule's minimum staffing standard. The district court erroneously considered it separately. 13

Applying the correct analysis, the district court would have found irreparable harm from this requirement sufficient to enjoin the whole Rule. Although CMS has consistently tried to downplay the resulting

sufficient to meet the nursing needs for all residents and greater consistency across facilities."); id. at 40,883 ("The [EFA requirement] . . . guard[s] against any attempts by LTC facilities to treat the minimum staffing standards included here as a ceiling, rather than a floor."); id. at 40,906 ("We proposed at new § 483.71(b)(4) that LTC facilities would have to use their facility assessment to develop and maintain a staffing plan to maximize recruitment and retention of nursing staff."); id. ("The facility assessment is an important complement to the minimum staffing requirements."); id. at 40,909 ("The facility assessment is the foundation for LTC facilities to assess their resident population and determine the direct care staffing and other resources, to provide the required care to their residents.").

¹² See, e.g., 89 Fed. Reg. at 49,909 ("The facility assessment must be conducted and developed with the intent of using it to inform decision making, especially about staffing decisions.").

requirement. But Plaintiffs have consistently challenged the entire Rule. See App. 445 n.5; R. Doc. 95 at 10 n.5. Indeed, Plaintiffs' motion for a preliminary injunction was replete with assertions that this requirement is vague and unreasonable. See, e.g., R. Doc 30-1 at 5, 7, 18–19. Plaintiffs never carved out the EFA requirement as permissible; that would have been impossible given its importance. Regardless, as noted above, Plaintiffs did not have to establish this requirement was unlawful independent of the staffing mandates in order to obtain a preliminary injunction.

harm, it has recognized that (A) Plaintiffs incurred costs from initially complying with the EFA requirement, and (B) Plaintiffs must annually review and update their EFAs to satisfy this requirement, meaning they will continually incur costs. That is enough. *Cf. Packard Elevator v. I.C.C.*, 782 F.2d 112, 115 (8th Cir. 1986). It is immaterial that the exact amount of money is uncertain because any unrecoverable harm suffices.

The EFA requirement has caused and will continue to cause Plaintiffs to spend money, meaning it irreparably harms them. Because Plaintiffs challenged the Rule as a whole, the district court should have considered this irreparable harm in light of the Rule's unlawful staffing mandates. The EFA requirement's irreparable harm warrants an injunction.

b. Staffing mandates

The Rule's staffing requirements also irreparably harm Plaintiffs.

The district court assumed that the 24/7 RN requirement and HPRD requirements "will impose tremendous costs on LTC facilities" that will be unrecoverable because of sovereign immunity. App. 447; R. Doc. 95

at 12. But instead of naturally and correctly proceeding to the merits, it somehow deemed these harms too speculative.

Plaintiffs submitted substantial evidence that they currently (and will continue to) incur costs from the 24/7 RN and HPRD requirements. Multiple Plaintiffs filed declarations conveying the changes many of their member LTC facilities are undertaking. For example, LeadingAge Virginia discussed how many of its nursing homes already were "attempting to hire additional RNs rather than [licensed practical nurses (LPNs)]" because of the 24/7 RN and HPRD requirements, and they were "increasing hiring efforts" more broadly because of the Rule. App. 267; R. Doc. 30-22 at 9. Similarly, LeadingAge Iowa affirmed its member facilities "are attempting to hire RNs over LPNs whenever possible" and engaging in expensive and aggressive recruitment strategies due to the Rule. App. 143; R. Doc. at 30-10 at 8.

The district court did not dispute these current costs, instead noting that Plaintiffs did not submit "cost breakdowns." App. 448; R. Doc. 95 at 13. But the district court cited no authority for its demand. A detailed cost breakdown was not required, and it would have done

nothing to change the facts contained within Plaintiff's uncontroverted evidence.

It is immaterial that the staffing mandates are not immediately effective. To comply with the relevant dates (the first little more than a year away), Plaintiffs must begin acting well in advance. The Rule acknowledges phased-in implementation of the mandates is necessary because it will take time for LTC facilities to fully comply:

In determining the question of the appropriate timeline for implementing [the minimum staffing requirements], we sought to strike a balance between . . . earlier implementation and assuring that the implementation of these changes is not so aggressive as to result in unintended facility closures . . . We strongly encourage all LTC facilities to begin working towards full compliance as quickly as possible.

89 Fed. Reg. at 40,911-12 (emphasis added).14

Plaintiffs—like CMS strongly encouraged—have already begun compliance efforts. See, e.g., App. 267; R. Doc. 30-22 at 9; App. 143; R. Doc. at 30-10 at 8. Hiring, particularly in a skilled and patient-centric profession like nursing, cannot occur overnight. LTC facilities must

¹⁴ See also 89 Fed. Reg. at 40,953 ("Finally, rather than requiring facilities to immediately meet the staffing requirements, we have taken a phased-in approach to the requirements to help ensure that an adequate workforce is available and to reduce the cost.").

ensure applicants are objectively qualified *and* that they would be a good fit for residents. It defies common sense and basic economic logic to conclude that a business that is required to meet staffing mandates by a firm deadline can wait until just before that deadline to begin hiring.

See Carpenters Indus. Council v. Zinke, 854 F.3d 1, 6 (D.C. Cir. 2017)

(Kavanaugh, J.); New York v. Yellen, 15 F.4th 569, 577 (2d Cir. 2021).

The shortage of qualified applicants only heightens the need for Plaintiffs to begin the hiring process well in advance. CMS has never contested the shortage; again, it knew about the shortage when it promulgated the Rule. *See, e.g.*, 89 Fed. Reg. at 40,880.

There is a set date by which Plaintiffs must comply with the staffing mandates, otherwise they will violate federal law. Each day that goes by, Plaintiffs must either (A) spend money and resources recruiting, hiring, and retaining trained nursing staff to give themselves the best opportunity to comply, or (B) do nothing in preparation for the mandates, sue at the last minute, and hope a court quickly issues a temporary restraining order. And if the latter occurred, CMS would undoubtedly fault Plaintiffs for waiting, particularly

because *CMS* encouraged them to act early. CMS cannot impose upon Plaintiffs this untenable and unreasonable choice.

The Rule's staffing mandates hurt Plaintiffs by requiring them to expend unrecoverable money and resources. That is irreparable harm.

c. The Rule uniquely harms State Plaintiffs

The Rule also imposes unique harms on State Plaintiffs. It requires them to engage in "institutional payment transparency reporting," *id.* at 40,995, and it will cost States of \$183,851 in the first year, *id.* at 40,991. States will have to devote staff resources to acquiring and organizing the information for these reports. *See, e.g.*, App. 102; R. Doc. 30-4 at 3. And they will incur additional costs posting these reports online. This reporting requirement is another burden for which State Plaintiffs must begin preparing now.

And the Rule will directly and naturally cause State Plaintiffs to spend resources on increased oversight of LTC facilities. States must process waiver requests and investigate complaints about alleged noncompliance with the Rule, *see* App. 91–93; R. Doc. 30-2 at 2–4; App. 118–19; R. Doc. 30-7 at 3–4; App. 102–04; R. Doc. 30-4 at 3–5, which are

likely to occur at high rates given the shortage of trained nurses, *see* App. 91–92; R. Doc. 30-2 at 2–3; App. 108–09; R. Doc. 30-5 at 2–3.

* * *

Plaintiffs can never "turn back the clock" on their compliance costs. *See Missouri*, 112 F.4th at 538. They cannot avoid these costs going forward. The Rule irreparably harms Plaintiffs, meaning only a preliminary injunction can provide relief.

II. Plaintiffs are likely to succeed on the merits

Plaintiffs must only be likely to succeed on one argument that the Rule is unlawful. They exceed that standard. The Rule fundamentally transforms a nationwide industry without clear congressional authorization, it conflicts with Congress's decision on LTC facility staffing, and it is arbitrary and capricious.

a. The Rule is unauthorized agency action that upends a nationwide industry

An agency may only act when empowered by Congress. And this is doubly true when the action has major economic ramifications. This means an agency cannot expand mundane statutory authorization into a broad mandate. Because the Rule upends the nursing home industry without clear congressional authorization, it is unlawful.

i. The Rule triggers the major questions doctrine

The Rule's substantial compliance costs and nationwide impact on the nursing home industry (and residents and their families) mean it falls within the major questions doctrine.

When an agency's action involves a matter of "vast economic and political significance," the agency must find clear congressional authority for its action. Alab. Ass'n of Realtors v. Dep't of Health and Hum. Servs., 594 U.S. 758, 764 (2021) (finding no clear congressional authority for the CDC to issue a nationwide eviction moratorium). This requirement is based on "both separation of powers principles and a practical understanding of legislative intent." West Virginia v. EPA, 597 U.S. 697, 723 (2022). Accordingly, courts scrutinize agency "assertions of 'extravagant statutory power over the national economy." Id. (quoting Util. Air Regul. Group v. EPA, 573 U.S. 302, 324 (2014)).

The Rule has vast economic and political significance. CMS proposes to revamp the entire nursing home industry to the tune of at

least \$43 billion dollars in compliance costs. The actual cost is likely much higher. The Supreme Court has held that \$50 billion qualifies as a Rule of vast economic significance. *Ala. Ass'n of Realtors*, 594 U.S. at 764. This Court has similarly recognized this rough trigger and applied the doctrine when appropriate. *See Missouri*, 112 F.4th at 537.

Beyond the costs, the breadth of authority CMS now asserts is monumental. The Rule fundamentally impacts 97% of all nursing homes and will put many of them out of business. And it exceeds the minimum staffing requirements for nursing homes in "nearly all states." 89 Fed. Reg. at 40,877.

When the major questions doctrine is triggered, there must be "clear authorization"—not some "vague statutory grant"—for the agency's conduct. West Virginia, 597 U.S. at 732; see also Missouri, 2025 WL 518130, at *10. CMS fails this test: It relies exclusively on a decades-old vague grant even though "[i]t is unlikely that Congress will make an extraordinary grant of regulatory authority through vague language in a long-extant statute." West Virginia, 597 U.S at 747 (cleaned up). Even worse (as discussed more below), the Rule conflicts with a separate statute by imposing staffing mandates like ones that

Congress (and agencies) rejected. This history underscores the absence of any clear authorization. *See id.* at 731 (rejecting agency action that Congress had already "considered and rejected"). Congress's decision, the "breadth of the authority" CMS now asserts, and the Rule's "economic and political significance" confirm that CMS cannot impose its mandates. *Id.* at 721.

Beyond the horizontal separation of powers, the major questions doctrine also protects federalism. As Justice Gorsuch observed in *West Virginia*, "When an agency claims the power to regulate vast swaths of American life, it not only risks intruding on Congress's power, it also risks intruding on powers reserved to the States." *Id.* at 744. (Gorsuch, J., concurring). CMS intruded on powers traditionally reserved to the States through the Rule's staffing mandates. Because Congress required only 8/7 RN staffing and allowed flexibility based on the needs of LTC facilities, States have added further requirements based on the needs of their residents and communities. Indeed, the Rule acknowledges that 38 States and D.C. have adopted their own varying staffing standards. *See* 89 Fed. Reg. at 40,881.

Given the Rule's impact on the nursing home industry, attendant significant cost, and displacement of States, it implicates the major questions doctrine. For the Rule to survive, CMS must point to express congressional authorization. But it cannot.

ii. Congress did not authorize the Rule

CMS must establish clear and express congressional authorization for the Rule. Indeed, CMS, like all administrative agencies, is a "creature[] of statute," so it "possess[es] only the authority that Congress has provided." Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin., 595 U.S. 109, 117 (2022). CMS "literally has no power to act . . . unless and until Congress confers power upon it." La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986); see also § 1302(a) (HHS Secretary may not "publish rules and regulations" that are "inconsistent with" the law).

The Supreme Court has cautioned that courts should be especially skeptical of agency action when the agency uses "a wafer-thin reed on which to rest such sweeping power." *Ala. Ass'n of Realtors*, 594 U.S. at 765. And it is an elementary principle that Congress "does not alter fundamental details of a regulatory scheme in vague terms or ancillary

provision." Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001). In other words, Congress "does not . . . hide elephants in mouseholes." Id. But CMS somehow believes the opposite.

CMS's belief falls short because (1) it uses "miscellaneous" authority to triple the minimum staffing hours Congress has already implemented, and (2) it uses that same "authority" to mandate staffing ratios that are nowhere to be found in the statute. Accepting that CMS possesses such broad authority would cast constitutional doubt upon its cherrypicked "authorization."

First, CMS has no authority to triple the requirement for the minimum amount of RN staffing necessary to participate in Medicaid or Medicare. Congress has already decided the issue: LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." § 1396r(b)(4)(C)(i); §1395i-3(b)(4)(C)(i). The Rule nevertheless seeks to alter this statutory requirement by mandating that an LTC facility "must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week." 89 Fed. Reg. at 40,997.

Again, CMS can only promulgate rules "pursuant to authority Congress has delegated to [it]." *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006). Tellingly, it relied not on the statutory provision that directly addresses minimum staffing but on "various provisions" elsewhere that apparently contain "separate authority" for this novel requirement, *id*. at 40,879, 40,890–91:

- a facility must meet "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," § 1396r(d)(4)(B);
 § 1395i-3(d)(4)(B);
- a facility must "provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care," § 1396r(b)(2); § 1395i-3(b)(2); and
- a facility must "care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident,"
 § 1396r(b)(1)(A); § 1395i-3(b)(1)(A).

Not one suffices. CMS concedes (as it must) that only the first provides any rulemaking authority. See App. 440; R. Doc. 95 at 5. And that authority permits only rules for "other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof[.]" This provision is under an "Other" subheading, which itself is under a "Miscellaneous" subheading, which itself is under: "Requirements Relating to Administration and Other Matters." § 1396r; § 1395i-3. It is impossible for this statute to be more divorced from the Rule. See Dubin v. United States, 599 U.S. 110, 120–21 (2023) (recognizing importance of considering headings in statutory interpretation); Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 221 (2012) (same). As demonstrated by its plain language, its location within the broader statutory scheme, and the relevant headings, the best reading of the statute is that it allows CMS to fill in administrative details concerning the health and safety of LTC facility patients that are not already covered by statute.

Congress already addressed mandatory staffing hours in a separate statutory provision, and it is implausible that CMS could have given itself the authority to alter that standard. CMS's general laws do

not give it this specific authority. After all, "[g]eneral language" in one part of a statute does not "apply to a matter specifically dealt with in another part of the same enactment." See, e.g., RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645–46 (2012) (quoting D. Ginsberg & Sons, Inc. v. Popkin, 285 U.S. 204, 208 (1932)). CMS seeks to invert that canon.

Even CMS recognized the statutes establishing the 8/7 RN requirement do not authorize it to modify Congress's standard; it disclaimed any reliance on those provisions. *See* 89 Fed. Reg. at 40,891. Yet CMS persisted, even asserting that the Rule "revises" the statutory 8/7 RN requirement. *See* 89 Fed. Reg. at 40,996. But Congress never authorized a revision. At most, it authorized filling certain gaps.

The 24/7 RN requirement lacks a colorable textual basis, much less clear authorization.

Second, the Rule's HPRD requirements fare no better. They are nowhere to be found in the relevant statutes. Congress carefully considered whether to enact quantitative staff-to-patient ratios for LTC facilities, and it chose not to do so. Instead, Congress implemented a qualitative standard in the underlying statutes, leaving staff-to-patient

ratios to the States: LTC facilities must provide nursing services "sufficient to meet the nursing needs of its residents." § 1396r(b)(4)(C)(i); § 1395i-3(b)(4)(C)(i).

The Rule unlawfully substitutes CMS's policy views for Congress's considered judgment. Instead of continuing to accommodate the wide variation of resident needs in different states and communities, CMS now mandates that each facility in each State meet arbitrary numerical thresholds. See 89 Fed. Reg. at 40,996.

Once again, CMS does not (because it cannot) rely on § 1395i-3(b)(4)(C) and § 1396r(b)(4)(C) as authority for these new requirements. And once again, it invokes vague authorizations of power that supposedly permit its mandates. See 89 Fed. Reg. at 40,879, 40,890–91.

None of those generalized provisions authorize CMS to impose nationwide HPRD requirements for RNs, NAs, and total nursing staff. General authority over Medicare and Medicaid does not permit it to modify "matter[s] specifically dealt with in another part of the same enactment." *RadLAX Gateway Hotel*, 566 U.S. at 646; *see also* § 1302(a).

Congress weighed the appropriate staffing levels, and it required that each facility maintain staffing levels "sufficient to meet the nursing

needs of its residents." § 1396r(b)(4)(C); § 1395i-3(b)(4)(C). CMS cannot use general authority to supersede Congress's judgment.

iii. Constitutional concerns

The only possible authorization for CMS to promulgate the Rule is a gap-filling catchall. But if Congress intended to give CMS such vast power through that provision, its decision would call into doubt that provision's constitutionality.

The constitutional doubt canon means this Court should interpret the Rule to avoid severe constitutional problems. As the Supreme Court has explained, its "application of the nondelegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta v. United States*, 488 U.S. 361, 373, n.7 (1989). The Supreme Court reads statutes with this principle in mind, e.g., Gundy v. United States, 588 U.S. 128, 145–48 (2019), and this Court should too.

If Congress truly gave CMS authority to implement a regulation that costs at least \$43 billion in compliance and overrides specific statutes, then it supplied no intelligible principle guiding the exercise of

that power. This would present serious nondelegation concerns that this Court should avoid by erring on the side of caution (*i.e.*, the separation of powers) and narrowly interpreting the statute. *See Kentucky v. Biden*, 23 F.4th 585, 607 n.14 (6th Cir. 2022) (rejecting "the government's interpretation" of a statute purportedly authorizing agency action in part because it "certainly would present non-delegation concerns").

* * *

The Rule upends the nursing home industry and imposes billions of dollars in compliance costs. And the best to which CMS can point to sustain the Rule is miscellaneous gap-filling authority. That is not enough, meaning the Rule is unlawful.

b. The Rule contradicts Congress's careful decision on staffing

Even if vague statutory provisions vested CMS with *some* authority to set staffing requirements, it cannot use that limited authority to contradict Congress. "Agencies may play the sorcerer's

apprentice but not the sorcerer himself." *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001). Here, CMS overstepped its authority.

Congress has already established the minimum amount of RN staffing necessary: LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." § 1396r(b)(4)(C)(i); § 1395i-3(b)(4)(C)(i). The Rule rewrites this statutory requirement in two ways.

First, Congress already established the minimum amount of RN staffing necessary to participate in Medicaid or Medicare: LTC facilities "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." § 1396r(b)(4)(C)(i); § 1395i-3(b)(4)(C)(i). The Rule replaces that 8/7 RN requirement with a 24/7 mandate. 89 Fed. Reg. at 40,997. CMS cannot rewrite a different universally applicable floor of 24/7 RN coverage into a statute that was enacted with an 8/7 RN floor.

Second, the Rule's waiver provisions only provide an 8-hour per day exemption to the 24-hour required staffing. 89 Fed. Reg. at 40,953. This means that an LTC facility will never be allowed to have less than 16 hours of nursing staff per day. Congress, on the other hand, provides

waivers even for its 8/7 requirement. See § 1396r(b)(4)(C)(ii); § 1395i-3(b)(4)(C)(ii). The Rule nullifies this statutory waiver.

Congress considered LTC facility staffing, and it determined the only appropriate standards to enforce nationwide. The Rule conflicts with Congress's decision, so it is unlawful.

c. The Rule is arbitrary and capricious

Even if CMS could promulgate the Rule (it could not) and the Rule did not conflict with statute (it does), the Rule still fails. It is the poster child of arbitrary and capricious rulemaking.

The APA's arbitrary-and-capricious standard requires agency action be "reasonable and reasonably explained." *See, e.g., Texas v. United States,* 40 F.4th 205, 226 (5th Cir. 2022) (quoting *FCC v. Prometheus Radio Project,* 592 U.S. 414, 423 (2021)). And a court "must set aside any action premised on reasoning that fails to account for relevant factors or evinces a clear error of judgment." *Id.*

An agency acts arbitrarily and capriciously when it departs sharply from prior practice without reasonable explanation or fails to reasonably consider alternatives to its action or reliance on the prior rule. Dep't of Homeland Sec. v. Regents of the Univ. of Cal., 591 U.S. 1, 29–31 (2020). An agency has also violated the APA when it

relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

In re Operation of Mo. River Sys. Litig., 421 F.3d 618, 628 (8th Cir. 2005).

When an agency ignores costs, it fails to consider an important part of the problem. *Michigan v. EPA*, 576 U.S. 743, 752–53 (2015). Indeed, considering costs "reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Id.* And when an agency changes longstanding policy, it must "show that there are good reasons for the new policy" and "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

By promulgating the Rule, CMS acted arbitrarily and capriciously because it (1) engaged in a sharp departure from past practice without reasonable explanation, (2) failed to consider reliance interests, and (3) failed to consider important aspects of the problem.

i. Sharp departure

First, CMS sharply departed from past practice without reasonable explanation. For 50 years, Defendants have consistently declined to deviate from Congress's directive by issuing staffing quotas. Most recently in 2016, CMS again rejected requests to adopt minimum-staffing rules, reiterating that it is not reasonable to adopt "a 'one size fits all' approach" toward LTC facilities. 81 Fed. Reg. at 68,755; see also id. at 68,754–56, 68,758.

What happened? Nothing, except a political promise. CMS relied on a single pretextual study to implement this Rule. But even the Abt Study did "not identif[y] a minimum staffing level to ensure safe and quality care." Abt Study at 115. Instead, it found that if a minimum staffing level was imposed, "[n]ursing homes [would] face barriers to hiring, primarily [with] workforce shortages and competition from staffing agencies." *Id.* at xi. While an agency may depart from past

practice, it must reasonably explain its departure by demonstrating good reason for it. *Encino Motorcars*, *LLC*, 579 U.S. at 221–22.

One study—which did not even conclude the staffing mandates were appropriate or feasible—does not cut it. CMS's failure to reasonably explain this sharp departure from 50 years of consistent practice is arbitrary and capricious.

ii. Reliance interests

Second, CMS failed to consider reliance interests. Even if CMS reasonably explained its sharp departure from past practice, it was still required to consider reliance interests. In the decades since Congress implemented the flexible staffing mandate, States have responded by implementing staffing requirements tailored to their citizens' needs. In turn, LTC facilities have devoted considerable resources to meeting the State requirements and working with local lawmakers to achieve workable standards. CMS concedes its 24/7 requirement is a one-size-fits-all "solution." 89 Fed. Reg. at 40,908. This approach is unworkable in a nation of diverse States, and it upends decades of intentional balance (set by Congress) between the States and the federal government.

A few examples exemplify the unique approaches adopted by States to ensure their senior citizens are protected:

- Kentucky does not set a numerical staffing requirement for nursing homes. Rather, it adopts a flexible approach requiring "twenty-four (24) hour nursing services with a sufficient number of nursing personnel on duty at all times to meet the total needs of residents." 902 Ky. Admin. Reg. 20:048, § 3(2)(a). Although Kentucky requires a charge nurse to always be on duty, a licensed practical nurse may serve in that role if an RN is on call. *Id.* § 2(10)(l).
- Missouri requires skilled nursing facilities have an RN on duty in the facility for the day shift, and either an LPN or RN for evening and night shifts. An RN also must be on call whenever only an LPN is on duty. And all residential care facilities must have at least one employee for every forty residents. In addition, Missouri LTC facilities must employ a licensed nurse for 8 hours per week per 30 residents to monitor each resident's condition and medication. 19 C.S.R. § 20-85.042; *id.* § 30-86.042–043.

- North Dakota has, for decades, set a minimum staffing
 requirement obligating facilities to have an RN on duty for 8
 hours per day. See N.D. Admin. Code § 33-07-03.2-14. As of the
 first quarter of 2023, only one of North Dakota's 76 nursing
 facilities would comply with the Rule's HPRD standards.
- West Virginia requires each nursing home to have an RN on duty in the facility for at least 8 straight hours, 7 days a week. W. Va. Code R. § 64-13-8.14.4. If an RN is not on duty, one must be on call. *Id.* § 64-13-8.14.5. West Virginia also requires nursing homes to provide at least "2.25 hours of nursing personnel time per resident per day." *Id.* § 64-13-8.14.1.

These varying standards sit alongside variations within the different States.

State Medicaid rates for nursing home services vary from \$170 per day to over \$400 per day. American Health Care Association (AHCA), Comment Letter on Proposed Rule 6 (Nov. 6, 2023), https://www.regulations.gov/comment/CMS-2023-0144-43877. Some States have a steady supply of RNs and NAs, while many others are already facing a massive shortage. *See, e.g.*, 89 Fed. Reg. at 40,957,

40,976; 81 Fed. Reg. at 6,755 (noting "geographic disparity in supply" of nursing staff). Rather than "highlight[ing] the need for national minimum-staffing standards," the "widespread variability in existing minimum staffing standards" adopted by 38 States and D.C. underscores that "different local circumstances . . . make different staffing levels appropriate (and higher levels impracticable) in different areas of the country." *Compare* 89 Fed. Reg. at 40,880, *with* AHCA Comment at 6. But CMS saw this State-by-State variation as self-evident justification for a universal rule, and it did not attempt to weigh the negative consequences of rigid nationwide requirements that "exceed the existing minimum staffing requirements in nearly all States." 89 Fed. Reg. at 40,877.

When an agency upends decades of state laws and practices relied upon by LTC facilities, it must seriously consider those reliance interests. *Encino Motorcars*, *LLC*, 579 U.S. at 221–22. CMS did not. It effectively ignored these interests by stating in general terms that increased staffing can lead to better outcomes in patients. But that is not a reasonable consideration of the decades-long flexibility employed

by States and LTC facilities. CMS's failure to meaningfully consider these interests was arbitrary and capricious.

iii. Important aspects of the problem

Finally, CMS failed to consider important aspects of the problem: both the virtual impossibility of complying with the mandates and the staggering compliance costs.

The Rule fails to consider that compliance is nearly impossible for many LTC facilities. The Rule imposes significant financial burdens on LTC facilities. Plaintiffs detailed the hardships they already face in hiring staff and the impossibility of implementing the Rule's minimum staffing requirements because of the inadequate supply of RNs and NAs in their communities. They also explained how the waivers and exemptions in the Rule provide no realistic assistance to their LTC facilities. See, e.g., App. 224–31; R. Doc. 30-18 at 7–15; App. 247–53; R. Doc. 30-20 at 3–9; App. 151–55; R. Doc. 30-11 at 7–11; see also AHCA Comment at 1–2, 5, 11–13, 18. CMS barely acknowledged this issue, noting merely that the new requirements "exceed the existing minimum staffing requirements in nearly all States" and will require increased

staffing "in more than 79 percent of nursing facilities nationwide." 89 Fed. Reg. at 40,877.

CMS estimates that LTC facilities will need to hire an additional 15,906 additional RNs to meet the 24/7 RN requirement and 0.55 RN HPRD requirement (an increase of about 11.8%), plus an additional 77,611 NAs to meet the 2.45 NA HPRD requirement and 3.48 total nurse HPRD requirement (an increase of about 17.2%). See id. at 40,958, 40,977–80. Those increases are unattainable at a time when many LTC facilities are already experiencing extreme difficulty finding qualified RNs and NAs to fill vacant positions, and when staffing shortages are expected only to worsen. See generally App. 188; R. Doc. 30-15; App. 145; R. Doc. 30-11; App. 217; R. Doc. 30-18; App. 245; R. Doc. 30-20. Put simply, "staffing mandates do not create more caregivers, nor do they drive caregivers to work in long term care." AHCA Comment at 1. The Rule also irrationally discounts the vital role of LPNs and licensed vocational nurses (LVNs), who hold nearly 230,000 jobs in LTC facilities across the country and undisputedly "provide important services to [their] residents." 89 Fed. Reg. at 40,881; see App. 152–55; R. Doc. 30-11 at 8–11; App. 127–29; R. Doc. 30-8 at 7–

9; App. 183–84; R. Doc. 30-14 at 16–17. As commenters pointed out, the Rule creates an incentive for LTC facilities "to terminate LPN/LVNs and replace them with . . . [less qualified] nurse aides" to meet the 2.45 NA HPRD requirement. 89 Fed. Reg. at 40,893.

Instead of meaningfully considering the near impossibility of compliance, CMS irrationally concluded that "[a] total nurse staffing standard [will] guard[] against" it. 89 Fed. Reg. at 40,893; *see* 88 Fed. Reg. at 61,366, 61,369. But that cannot be right.

For example, a facility that already provides high-quality care through average staffing of 0.55 RN HPRD, 1.25 LVN/LPN HPRD, and 1.7 NA HPRD would satisfy the 3.48 total nurse HPRD requirement but would need another 0.75 NA HPRD to satisfy the 2.45 NA HPRD requirement. See, e.g., App. 286–87; R. Doc. 30-25 at 2–3 (Dooley Center staffing includes 4.64 total nurse HPRD but it would have failed the Rule's required 0.55 RN HPRD 39% of the time). The Rule pressures LTC facilities to replace experienced LPNs/LVNs with less-qualified new hires to meet CMS's arbitrary quota of 2.45 NA HPRD.

The Rule does not deny that there are not nearly enough RNs and NAs available for the 79 percent of LTC facilities that do not currently

comply with the new mandates. CMS asserted that the Rule's phase-in period will "allow all facilities the time needed to prepare and comply with the new requirements specifically to recruit, retain, and hire nurse staff as needed." 89 Fed. Reg. 40,894. But more time does not mean more nurses will suddenly become available. The Rule is a mandate that many LTC facilities will be unable to meet.

There is no reason to believe the shortage of RNs and NAs will materially ease in the near future. In fact, it will likely worsen, as "hundreds of thousands [of nursing professionals] are expected to retire or leave the health care profession entirely in the coming years." AHCA Comment at 5; see also id. at 2 ("The phase-in provisions are frankly meaningless considering the growing caregiver shortage."); App. 225–27; R. Doc. 30-18 at 9–11 (describing dire trends in healthcare workforce); App. 151–52; R. Doc. 30-11 at 7–8; (similar); App. 192–95; R. Doc. 30-15 at 5–8 (similar). CMS somehow, someway, "fully expect[s] that LTC facilities will be able to meet [the Rule's] requirements," 89 Fed. Reg. at 40,894, but Plaintiffs' evidence shows that is a pipe dream.

The Rule's "hardship exemption" does nothing to alleviate the burden. For starters, such exemptions are available only to facilities that have been surveyed and cited for failure to meet the new staffing standards—and "facilities cannot request" (or receive) "a survey specifically for the purpose of granting an exemption." 89 Fed. Reg. at 40,902. So instead of being able to proactively explain why they should be entitled to an exemption, facilities that cannot meet the arbitrary requirements will face a perpetual risk of being sanctioned for non-compliance. See AHCA Comment at 6, 33–34.

CMS repeatedly emphasizes that the hardship exemption is meant for "limited circumstances," 89 Fed. Reg. at 40,894, and that many facilities in areas of the country with severe shortages of available RNs and NAs would not qualify for an exemption because there are so many "other requirements" that must be met "to obtain an exemption," *id.* at 40,953; *see also, e.g.*, App. 251–52; R. Doc. 30-20 at 7–8 (describing unachievable nature of waiver and exemptions for LTC facilities); App. 155; R. Doc. 30-11 at 11 (similar). The complete lack of viable exemptions confirms CMS did not consider the virtual impossibility of compliance.

Additionally, the Rule fails to reasonably consider its staggering costs. According to CMS, the Rule will cost over \$5 billion per year to

implement once fully phased in. See 89 Fed. Reg. at 40,949, 40,970. Other estimates place the costs as high as \$7 billion per year. See id. at 40,950. The Rule does not provide any additional Medicare or Medicaid funding, so it "assume[s] that LTC facilities . . . will bear the[se] costs." Id. at 40,949. But LTC facilities are in no position to take on this huge financial burden. AHCA Comment at 5. Almost 60 percent of LTC facilities already have negative operating margins; more than 500 LTC facilities closed over the course of the COVID-19 pandemic; and the costs associated with these new staffing mandates would likely force many more facilities to close. *Id.* at 5; see also, e.g., App. 153–54; R. Doc. 30-11 at 9-10 (estimated costs for Kansas facilities to comply with Rule on minimum staffing standards range between \$64 million and \$92.7 million in the first year, at an average annual cost of \$211,905 per facility); App. 125–26; R. Doc. 30-8 at 5–6 (estimating total cost of \$20 million for South Dakota facilities to comply with Rule).

This massive, unfunded staffing mandate, despite the ongoing workforce crisis and economic realities, is neither "reasonable" nor "reasonably explained." *Cf. Texas*, 40 F.4th at 226. CMS touted a new initiative that seeks to encourage people to pursue careers in nursing by

"investing over \$75 million in financial incentives such as tuition reimbursement." 89 Fed. Reg. 40,894. But this "one-time workforce effort" is a drop in the bucket compared to the funding that will be needed to train the additional nursing staff necessary to meet the new mandates. AHCA Comment at 23. It "is not going to fix the workforce crisis." *Id.* This complete failure to consider the impact of at least \$43 billion in regulatory costs on LTC facilities with almost no assistance from the federal government is arbitrary and capricious.

* * *

The Rule violates the APA because it is arbitrary and capricious.

III. The equities and public interest lie with Plaintiffs

The equities and the public interest support preliminarily enjoining the Rule. *See Missouri*, 2025 WL 518130, at *11 (recognizing the equities and public interest merge when "the federal government is the party opposing the injunction").

In considering injunctive relief, this Court asks "whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined." *Nebraska*, 52 F.4th at 1046 (quoting *Glenwood Bridge*,

Inc. v. City of Minneapolis, 940 F.2d 367, 370 (8th Cir. 1991)). The Rule upends the nursing home industry despite near-impossible compliance. Given its "irreversible impact," this Court should enjoin the Rule while this case proceeds. See id. at 1047.

A preliminary injunction will not harm CMS because it will simply be unable to enforce an unlawful regulation. *See Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994) (agency suffers no harm when it is prohibited from acting "in violation of applicable statutory restraints"). Nor can CMS commandeer the alleged harm to third parties. *Cf. Kansas v. United States*, 124 F.4th 529, 533–34 (8th Cir. 2024) (per curiam).

The public interest further supports Plaintiffs. "There is generally no public interest in the perpetuation of unlawful agency action." Shawnee Tribe v. Mnuchin, 984 F.3d 94, 102 (D.C. Cir. 2021). And where, as here, Plaintiffs have shown a strong likelihood of success on the merits, it is "a strong indicat[ion] that a preliminary injunction would serve the public interest." Id. The public interest is not served by imposing arbitrary and unattainable staffing mandates on nursing

homes that will drive up costs and lead to them shutting down. The public interest and equities lie with Plaintiffs.

IV. Nationwide relief is necessary

In issuing an injunction, this Court must decide whether limited or nationwide relief is appropriate. This Court should choose the latter. The nursing home industry is a nationwide industry, and the Rule has nationwide impacts.

An injunction is a matter of equity, and "the scope of injunctive relief is dictated by the extent of the violation established, not by the geographical extent of the plaintiff class." *Nebraska*, 52 F.4th at 1048 (quoting *Rodgers v. Bryant*, 942 F.3d 451, 458 (8th Cir. 2019)). ¹⁵ Plaintiffs have established that the Rule is unlawful in multiple

This equitable principle aligns with the law on vacatur, where the "default remedy" when a regulation is found unlawful "is to set aside or vacate the rule." *Missouri*, 2025 WL 518130, at *11; *see also Nat'l Min. Ass'n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (recognizing the "ordinary result" when "a reviewing court determines that agency regulations are unlawful" is that "the rules are vacated—not that their application to the individual petitioners is proscribed."); *Barr v. Am. Ass'n of Pol. Consultants, Inc.*, 591 U.S. 610, 627 n.8 (2020) (explaining that when "a provision is declared invalid," it "cannot be lawfully enforced against others"). In other words, the unlawful Rule would not be permitted to affect *anyone*. In much the same way, a nationwide preliminary injunction prevents the unlawful Rule from being applied to anyone, too.

respects, and not merely invalid as applied to any one Plaintiff. For this

reason, the Rule should be enjoined nationwide. See D.C., 444 F. Supp.

3d at 49 ("That a nationwide remedy is necessary to provide complete

relief for promulgation of an unlawful rule follows from the nature of

the claim that the rule is facially unlawful.").

Additionally, injunctive relief must be "workable" and no more

burdensome than necessary. Nebraska, 52 4th at 1048. Given the

diverse coalition of Plaintiffs in this case and nationwide reach of the

nursing home industry, a piecemeal injunction would be both

unworkable and unduly burdensome. A nationwide injunction would

provide certainty. See Missouri, 2025 WL 518130, at *11.

The Rule's harm and illegality are not limited to the specific

Plaintiffs here, so this Court should enjoin the Rule nationwide.

CONCLUSION

For the foregoing reasons, this Court should reverse.

Dated: March 3, 2025

66

Respectfully submitted,

KRIS W. KOBACH

Kansas Attorney General

/s/ Anthony J. Powell

Anthony J. Powell

Solicitor General

Adam T. Steinhilber

Assistant Solicitor General

James R. Rodriguez

Assistant Attorney General

Office of the Kansas Attorney

General

120 SW 10th Avenue, 2nd Floor

Topeka, Kansas 66612

Telephone: (785) 296-2215

Fax: (785) 296-3131

anthony.powell@ag.ks.gov

adam.steinhilber@ag.ks.gov

jay.rodriguez@ag.ks.gov

Counsel for the State of Kansas

BRENNA BIRD Attorney General of Iowa

/s/ Eric H. Wessan

Eric H. Wessan Solicitor General 1305 E. Walnut Street Des Moines, Iowa 50319 Phone: (515) 823-9117

Email: Eric.Wessan@ag.iowa.gov

Counsel for the State of Iowa

ALAN WILSON Attorney General of South Carolina

/s/ Joseph D. Spate

Joseph D. Spate

Assistant Deputy Solicitor General

Office of the South Carolina

Attorney General

1000 Assembly Street

Columbia, South Carolina 29201

Phone: (803) 734-3371

Email: josephspate@scag.gov Counsel for the State of South

Carolina

STEVE MARSHALL Alabama Attorney General

/s/ Edmund G. LaCour Jr.

Edmund G. LaCour Jr.

Solicitor General

Office of the Attorney General

State of Alabama

501 Washington Avenue

P.O. Box 300152

Montgomery, Alabama 36130-

0152

Phone: (334) 242-7300

Email:

Edmund.LaCour@alabamaag.gov Counsel for the State of Alabama

TREG TAYLOR Attorney General of Alaska

Cori M. Mills

Deputy Attorney General of Alaska

/s/ Laura O. Russell

Laura O. Russell

Assistant Attorney General

Alaska Department of Law

1031 West 4th Avenue, Suite 200

Anchorage, Alaska 99501-1994

Phone: (907) 269-5100

Email: laura.russell@alaska.gov Counsel for the State of Alaska

TIM GRIFFIN Arkansas Attorney General

/s/ Dylan L. Jacobs

Dylan L. Jacobs

Deputy Solicitor General

Office of the Arkansas Attorney

General

323 Center Street, Suite 200

Little Rock, AR 72201

Phone: (501) 682-2007

Email:

Dylan.Jacobs@arkansasag.gov

Counsel for the State of Arkansas

JAMES UTHMEIER Florida Attorney General

/s/ Caleb A. Stephens

Caleb A. Stephens

Allen Huang

Office of the Attorney General

The Capitol, Pl-01

Tallahassee, Florida 32399-1050

Phone: (850) 414-3300

Email:

caleb.stephens@myfloridalegal.com

allen.huang@myfloridalegal.com Counsel for the State of Florida

CHRISTOPHER M. CARR Attorney General of Georgia

/s/ Stephen J. Petrany

Stephen J. Petrany

Solicitor General

Office of the Attorney General

40 Capitol Square, SW

Atlanta, Georgia 30334

Phone: (404) 458-3408

Email: spetrany@law.ga.gov

Counsel for the State of Georgia

RAÚL R. LABRADOR Attorney General of Idaho

/s/ Nathan S. Downey

Nathan S. Downey

David H. Leroy Fellow

Office of the Attorney General

PO Box 83720,

Boise, Idaho 83720

Phone: (208) 334-2400

Email:

Nathan. Downey@ag. idaho. gov

Counsel for the State of Idaho

THEODORE E. ROKITA Attorney General of Indiana

/s/ James A. Barta

James A. Barta Solicitor General

Indiana Attorney General's

Office

IGCS – 5th Floor

302 W. Washington St. Indianapolis, IN 46204

Phone: (317) 232-0709

Email: james.barta@atg.in.gov

Counsel for the State of Indiana

RUSSELL COLEMAN Attorney General of Kentucky

/s/ Matthew F. Kuhn

Matthew F. Kuhn Solicitor General

Kentucky Office of the Attorney

General

700 Capital Avenue, Suite 118

Frankfort, Kentucky 40601

Phone: (502) 696-5300

Email: Matt.Kuhn@ky.gov

Counsel for the Commonwealth of

Kentucky

ANDREW BAILEY Attorney General of Missouri

/s/ Victoria S. Lowell

Victoria S. Lowell

Assistant Attorney General

Office of the Missouri Attorney

General

815 Olive Street, Suite 200

St. Louis, Missouri 63101

Phone: (314) 340-4792

Email:

Victoria.lowell@ago.mo.gov

Counsel for the State of Missouri

AUSTIN KNUDSEN Attorney General of Montana

/s/ Peter M. Torstensen, Jr.

Peter M. Torstensen, Jr.

Deputy Solicitor General

Montana Department of Justice

215 North Sanders

P.O. Box 201401

Helena, Montana 59620-1401

Phone: (406) 444.2026

Email: peter.torstensen@mt.gov

Counsel for the State of Montana

MICHAEL T. HILGERS Attorney General of Nebraska

GENTNER DRUMMOND Attorney General of Oklahoma

/s/ Zachary B. Pohlman Zachary B. Pohlman Assistant Solicitor General Office of the Nebraska Attorney General 2115 State Capitol Lincoln, Nebraska 68509

Phone: (402) 471-2682

Email:

Zachary.Pohlman@Nebraska.gov Counsel for the State of Nebraska /s/ Garry M. Gaskins Garry M. Gaskins, II Solicitor General Office of Attorney General State of Oklahoma 313 N.E. 21st St. Oklahoma City, OK 73105 Phone: (405) 521-3921 Garry.Gaskins@oag.ok.gov Counsel for the State of Oklahoma

DREW H. WRIGLEY North Dakota Attorney General

/s/ Philip Axt Philip Axt Solicitor General Office of Attorney General 600 E. Boulevard Ave Dept. 125 Bismarck, North Dakota 58505

Phone: (701) 328-2210 Email: pjaxt@nd.gov

Counsel for the State of North

Dakota

MARTY J. JACKLEY Attorney General of South Dakota

/s/ Amanda Miiller Amanda Miiller Deputy Attorney General Office of the Attorney General State of South Dakota 1302 E. Hwy. 14, Suite #1 Pierre, South Dakota 57501 Phone: (605) 773-3215 Email: amanda.miiller@state.sd.us Counsel for the State of South Dakota

DEREK BROWN Attorney General of Utah

/s/ Stephanie M. Saperstein
Stephanie M. Saperstein
Assistant Attorney General
Office of Utah Attorney General
195 North 1950 West
Salt Lake City, Utah 84116
Phone: (801) 680-7690
Email:
stephaniesaperstein@agutah.gov
Counsel for Plaintiff State of

Utah

JASON S. MIYARES Attorney General of Virginia

/s/ Kevin M. Gallagher
Kevin M. Gallagher
Principal Deputy Solicitor General
Virginia Office of the Attorney
General
202 North 9th Street
Richmond, Virginia 23219
Phone: (804) 786-2071
Fax: (804) 786-1991
Email: kgallagher@oag.state.va.us
Counsel for the Commonwealth of
Virginia

JOHN B. MCCUSKEY Attorney General of West Virginia

/s/ Michael R. Williams

Michael R. Williams
Solicitor General

Office of the Attorney General of

West Virginia

State Capitol Complex

Building 1, Room E-26

Charleston, WV 25301

Phone: (304) 558-2021

Email:

michael.r.williams@wvago.gov Counsel for Plaintiff State of

West Virginia

/s/ Anna St. John

Anna St. John

Hamilton Lincoln Law Institute

1629 K St. NW Suite 300

Washington, DC 20006

(917) 327-2392

anna.stjohn@hlli.org

Counsel for Plaintiffs LeadingAge

 $Kansas, Leading Age\ South$

Carolina, LeadingAge Iowa,

 $Leading Age\ Colorado,\ Leading Age$

Maryland, LeadingAge Michigan,

LeadingAge Minnesota,

LeadingAge Missouri, LeadingAge

Nebraska, LeadingAge New Jersey/Delaware, LeadingAge Ohio, LeadingAge Oklahoma,

LeadingAge PA, South Dakota Association of Healthcare

Organizations, LeadingAge

Southeast, LeadingAge Tennessee,

LeadingAge Virginia, Dooley

Center, Wesley Towers

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Opening Brief of Appellants complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B)(i) because it contains 12,925 words, excluding the parts exempted by Fed. R. App. P. 32(f), as calculated by the word-counting function of Microsoft Word.

Further, I certify that the foregoing Opening Brief of Appellants complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface—14-point Century Schoolbook—using Microsoft Word.

Pursuant to Circuit Rule 28A(h)(2), I certify that the foregoing Opening Brief of Appellants and the contemporaneously filed Addendum to the Opening Brief of Appellants have been scanned for viruses and are virus free.

/s/ Anthony J. Powell
Anthony J. Powell
Counsel for the State of Kansas

CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2025, the foregoing Opening Brief of Appellants and the contemporaneously filed Addendum to the Opening Brief of Appellants were electronically filed with the Clerk of the Court using the CM/ECF system. I further certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Anthony J. Powell
Anthony J. Powell
Counsel for the State of Kansas